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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/730,831	12/09/2003	Wayne P. Franco	0147-DIV1	5378

7590 10/25/2004

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EXAMINER	
NICHOLS, CHRISTOPHER J	

ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 10/25/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/730,831	FRANCO, WAYNE P.	
	Examiner	Art Unit	
	Christopher J Nichols, Ph.D.	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 December 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *16-30* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *16-30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *16 September 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *4.26.04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of Application, Amendments, and/or Claims

1. The Preliminary Amendment filed 9 December 2003 has been received and entered in full.

2. The Preliminary Amendment filed 16 September 2004 has been received and entered in full.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

3. Claims **16, 17, 19, 24,** and **26,** are rejected under 35 U.S.C. 102(a) and 102(e) as being anticipated by US 5,932,540 (3 August 1999) Hu *et al.*

4. '540 teaches intranasal administration of VEGF2, a growth factor, to treat coronary artery disease including but not limited to myocardial infarction and ischemia thus meeting the limitations of claims 16, 17, 19, 24, and 26 (Col. 1-2; Col. 10-11; Col. 16-17; Col. 19-20).

5. Claims **16, 17, 18, 20, 21, 22, 23, 24, 25, 27, 28, 29,** and **30** are rejected under 35 U.S.C. 102(e) as being anticipated by US 6,239,172 (29 May 2001) Kaesemeyer.

6. '172 teaches intranasal administration of VEGF or bFGF to treat coronary artery disease including but not limited to coronary thrombosis and restenosis post angioplasty (a type of reperfusion) thus meeting the limitations of claims 16, 17, 18, 22, 23, 24, 25, 29, and 30 (Col. 2-3, 5).

7. '172 teaches that the pharmaceutical composition comprising VEGF or bFGF may be an aqueous solution (an aerosol when administered intranasally) or a lyophilized (a process which yields a dry crystalline powder) thus meeting the limitations of claims 20, 21, 27, and 28 (Col. 8-9).

8. Claims **16, 17, 19, 20, 21, 24, 26, 27,** and **28** are rejected under 35 U.S.C. 102(e) as being anticipated by US 6,475,796 B1 (5 November 2002) Pollitt & Abraham.

9. '796 teaches intranasal administration of VEGF a growth factor, to treat coronary artery disease thus meeting the limitations of claims 16, 17, 19, 24, and 26 (Col. 1, 4-5, 8-10, 18).

10. '796 teaches that the pharmaceutical composition comprising VEGF may be an aerosol or a dry powder thus meeting the limitations of claims 20, 21, 27, and 28 (Col. 18-19).

11. Claims **16, 17, 19, 20, 21, 22, 23, 24, 26, 27, 28, 29,** and **30** are rejected under 35 U.S.C. 102(e) as being anticipated by US 6,620,784 B1 (16 September 2003) Ferrara & Kuo.

12. '784 teaches intranasal administration of VEGF a growth factor, to treat coronary artery disease including but not limited to reperfusion injury such as restenosis subsequent to balloon angioplasty thus meeting the limitations of claims 16, 17, 19, 22, 23, 24, 26, 29, and 30 (Col. 1, 4-5, 7, 9-10, 13-14, 42, 50).

13. '784 teaches that the pharmaceutical composition comprising VEGF may be a nose spray (an aerosol) or a dry powder thus meeting the limitations of claims 20, 21, 27, and 28 (Col. 46-52).

14. '784 teaches that the pharmaceutical composition comprising VEGF may be made and used in combination with other growth factors including but not limited to bFGF and/or aFGF thus meeting the limitations of claims 16, 17, and 24 (Col. 52).

15. Claims **16, 17, 18, 20, 21, 24, 25, 27,** and **28** are rejected under 35 U.S.C. 102(e) as being anticipated by US 6,737 404 B2 (18 May 2004) Springer *et al.*

16. '404 teaches intranasal administration of bFGF a growth factor, to treat coronary artery disease including thus meeting the limitations of claims 16, 17, 18, 24, and 25 (Col. 3, 5-7, 11-14).

17. '404 teaches that the pharmaceutical composition comprising bFGF may be an aqueous solution (an aerosol) or a lyophilized formulization (a dry powder) thus meeting the limitations of claims 20, 21, 27, and 28 (Col. 14).

18. '404 teaches that the pharmaceutical composition comprising bFGF may be made and used in combination with other growth factors including but not limited to bFGF thus meeting the limitations of claims 18 and 24 (Col. 14).

Summary

19. No claims are allowed.

20. The Examiner notes that bFGF is also known as basic FGF and FGF-2 [see Bikfalvi *et al.* (1997) "Biological Roles of Fibroblast Growth Factor-2." Endocrine Reviews **18**(1): 26-45].

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Christopher James Nichols, Ph.D.** whose telephone number is **(571) 272-0889**. The examiner can normally be reached on Monday through Friday, 8:00 AM to 5:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Brenda Brumback** can be reached on **(571) 272-0961**.

The fax number for the organization where this application or proceeding is assigned is **703-872-9306**.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see **http://pair-direct.uspto.gov**. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at **866-217-9197** (toll-free).

Elizabeth C. Kemmerer

CJN
October 19, 2004

ELIZABETH KEMMERER
PRIMARY EXAMINER